

July 2002



Minnesota Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Actions

During the months of March, April, and May, the Minnesota Board of Pharmacy took the following disciplinary actions on its licensees.

Astrup, Daniel B., License #113575-4. Licensee surrendered his license to practice pharmacy subsequent to allegations that he violated the terms of his probation with the Board.

Darling, Douglas J., License #111251-5. License was revoked as a result of a notice from the Department of Revenue that he was delinquent in payment of taxes. Revocation remains in effect until a clearance certificate is issued by the Minnesota Department of Revenue.

Melhus, Jacquelyn L., License #111261-2. License was revoked as a result of a notice from the Department of Revenue that she was delinquent in payment of taxes. Revocation remains in effect until a clearance certificate is issued by the Minnesota Department of Revenue.

Dispensing Errors and Staffing Levels – Is There a Connection?

As regular readers of this *Newsletter* are aware, the Board is very concerned with the issue of dispensing errors and the fact that studies have shown that 80-90% of the errors made in the dispensing activities of a pharmacy can be identified and corrected prior to reaching the patient during appropriate patient counseling.

Pharmacists-in-charge at Minnesota pharmacies are responsible under MN Rule 6800.2400, Subp. 1.J., “to ensure that staffing and operational quality assurance policies are developed, implemented, and followed for the purpose of decreasing and monitoring prescription errors.”

During the investigation of dispensing errors that come to the Board’s attention, Board inspectors will be looking at staffing levels and operational quality assurance policies in accordance with this rule.

Pharmacists-in-charge are encouraged to perform a self-assessment on their pharmacy to assure compliance with these requirements.

Continuing Education Reporting Coming Up Soon

While a fair number of Minnesota licensed pharmacists have already reported the completion of their continuing education

requirements for the period October 1, 2000 - September 30, 2002, the majority of Minnesota pharmacists are still completing their continuing education requirements.

Please keep in mind that, unless you are one of the pharmacists randomly selected for continuing education auditing, you do not need to submit proof of attendance for your continuing education programs. Once you have completed the continuing education requirement, simply complete the continuing education certification statement that was previously sent to you and return it to the Minnesota Board of Pharmacy office.

Those pharmacists randomly selected for auditing will be notified in late summer that they will need to submit proof of attendance for all of their continuing education participation.

Guidelines on the Use of Automated Counting Machines

As pharmacies are becoming busier, many are turning to automation in the form of the automated counting machines to assist in the prescription-filling process.

The Board of Pharmacy has developed some guidelines regarding the use of automated counting machines. Pharmacists should note that because Board of Pharmacy rules require pharmacists to “check the original labeled container from which the medication was withdrawn” as part of the certification process, a variance will be necessary for pharmacies that will be installing automated counting devices.

Below are the Board’s guidelines that should be consulted when contemplating the purchase of automated counting machines.

Automated Counting Machine Guidelines

The Board of Pharmacy must be notified in writing, before distributing, dispensing, or vending any legend drug by automatic or vending machine. The written notification must include the name and address of the pharmacy responsible for control of the system, and the name of the pharmacist-in-charge of the pharmacy. Policies and procedures should also be included with the notification. See **MN Rule 6800.2600**.

1. All filling of cells/cassettes needs to be addressed as pre-packaging, with compliance and documentation of all steps in **MN Rule 6800.3200, Subp. 1**.
2. All filling of cells/cassettes should be done with only one drug at a time.

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Developments in the Office-Based Treatment of Narcotic Addiction; DEA Proposes to Reschedule Buprenorphine

New legislation, together with new opioid treatment medications will for the first time permit physicians to prescribe certain opioid treatment medications to treat opiate addiction. These developments will generate new activities and responsibilities for pharmacists, as well as retail, institutional, and community pharmacies.

The Drug Addiction Treatment Act (DATA, P.L. 106-310) enacted in 2000 amends the Controlled Substances Act (CSA) to allow qualified physicians to apply for waivers of the Narcotic Addiction Treatment Act and the CSA registration, so that they may dispense or prescribe certain Schedule III, IV, or V controlled narcotic substances specifically approved by the Food and Drug Administration (FDA) for narcotic addiction treatment. Although there are no FDA-approved narcotic treatment medications at this time, products are in the final stages of FDA review.

Importantly, DATA includes a preemption clause that stipulates that until October 2003, states may *not* preclude practitioners from dispensing/prescribing Schedule III, IV, or V, approved (for the treatment of opiate addiction) narcotic drugs, *unless* a state enacts new legislation during that time prohibiting dispensing of such drugs.

To be eligible for a waiver, qualified practitioners (physicians) must submit a written notification of intent to the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT). The physicians must have a state license to practice medicine and a US Drug Enforcement Administration (DEA) registration to dispense controlled substances. In the notification, physicians must certify that they will treat no more than 30 patients (individual or in group practice), and that they have the capacity to refer patients for ancillary services. In addition to these certifications, physicians must meet the following criteria to qualify for a waiver:

- ◆ Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties (ABMS), or;
- ◆ Addiction certification from the American Society of Addiction Medicine (ASAM), or;
- ◆ Subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA), or;
- ◆ With respect to the treatment and management of opiate-dependent patients, the physician has completed not less than eight hours of training provided by ASAM, the American Academy of Addiction Psychiatry, the American Medical Association, AOA, the American Psychiatric Association, or any other organization the Secretary of the Department of Health and Human Services (HHS) determines is appropriate for these purposes, or;
- ◆ Participation as an investigator in one or more clinical trials leading to the approval of a narcotic drug in Schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug, or;
- ◆ Other training or experience as the state medical licensing board (of the state in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients, or;

- ◆ The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

Additional information on DATA, including a Standard Notification form, may be found at www.buprenorphine.samhsa.gov. The Federation of State Medical Boards (FSMB) has developed Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office. These guidelines may be referenced from the FSMB Web site at www.fsmb.org.

Pharmacists have expressed an interest in obtaining additional information to help verify whether a physician has a valid waiver. CSAT is currently taking steps to assist pharmacists in verifying a physician's waiver status. Pharmacists will be able to access the SAMHSA Treatment Facility Locator at <http://findtreatment.samhsa.gov> and access a list of physicians with waivers. Pharmacists may also contact the CSAT Buprenorphine Information Center at 866/BUP-CSAT, or via e-mail at info@buprenorphine.samhsa.gov.

As an important related matter, the DEA published a proposed rule in the March 21, 2002 *Federal Register* that would reschedule buprenorphine from a Schedule V to a Schedule III narcotic. This DEA action is based upon a formal rescheduling recommendation by HHS. The DEA rescheduling proposal is based upon new information available since the initial scheduling review of buprenorphine in the early 1980s. The rescheduling action, when finalized, will not affect the use of buprenorphine products approved by FDA for the treatment of opiate addiction. The notice states that FDA has issued approvable letters for two products and they are likely to receive final marketing approval in 2002.

FDA Warns Sellers of Nicotine Lollipops, Lip Balm to Discontinue Marketing Products

In an April 10, 2002 *Talk Paper*, the US Food and Drug Administration (FDA) announced that it issued warning letters to three pharmacies selling nicotine lollipops and/or nicotine lip balm over the Internet stating that the products are illegal and that sales of the products must be discontinued.

The FDA is concerned about the health risk associated with these products, which are promoted on the Internet sites as smoking cessation aides or to treat addiction. According to FDA, the lollipops and lip balms appear to be compounded or dispensed without a doctor's prescription, contain a form of nicotine that is not used in FDA-approved smoking cessation products, and present a risk of accidental use by children because of their candy-like appearance.

The products cited in the letters include compounds incorporating nicotine salicylate, natural sweeteners, and flavorings in a sugar-free base, compounded into 0.5 mg, 1 mg, 2 mg, and 4 mg dosages.

For more information, visit the FDA Web site at www.fda.gov.

DEA Final Rule Amends Comprehensive Methamphetamine Control Act of 1996

The US Drug Enforcement Administration (DEA) published a final rule in the March 28, 2002 *Federal Register* amending its regulations to implement the requirements of the Comprehensive Methamphetamine Control Act of 1996 (MCA) with respect to the regulation of pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products as List I chemicals, and the

Compliance News

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reporting of certain transactions involving pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products. The rule became effective April 29, 2002.

The MCA removed the previous exemption from regulation as List I chemicals, which had applied to pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products, making persons who distribute the products subject to the registration requirement. In addition, distributions, importations, and exportations of the products became subject to the existing chemical controls relating to regulated transactions, except in certain circumstances specified in the MCA. The MCA requires that reports be submitted for certain distributions involving pseudoephedrine, phenylpropanolamine, and ephedrine (including drug products containing those chemicals) by Postal Service or private or commercial carrier to nonregulated persons.

This final rule amends the regulations to make them consistent with the language of the MCA and to establish specific procedures to be followed to satisfy the new reporting requirement.

For additional information about the final rule, contact Patricia M. Good, chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone 202/307-7297. Or visit the US DEA Web site at www.deadiversion.usdoj.gov/fed_regs/rules/2002/fr0328.htm.

Beware of Erroneous Daily Oral Methotrexate Dosing

This column was prepared by the Institute for Safe Medication Practices (ISMP).

ISMP is an independent nonprofit agency that works closely with US Pharmacopeia (USP) and the Food and Drug Administration (FDA) in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Road, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.



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The perils of low-dose oral methotrexate are clearly evident in the dozens of fatalities reported in patients who have been prescribed this cytotoxic agent for alternative conditions. While methotrexate has a well-established role in oncology, increasingly it's being used in low doses for immunomodulation in rheumatoid arthritis, asthma, psoriasis, inflammatory bowel disease, myasthenia gravis, and inflammatory myositis. Used for these purposes, it's administered as a weekly dose. But mistakes have been all too frequent because relatively few medications are dosed in this manner and clinicians and patients are much more familiar with daily dosing of medications. For example, one patient died after he misunderstood the directions for use and took methotrexate 2.5 mg every 12 hours for six consecutive days, instead of 2.5 mg every 12 hours for three doses each week. Another patient died after he

misread the directions on a prescription bottle and took 10 mg every "morning" instead of every "Monday." Errors also have been reported with hospitalized patients. In one case, the physician had properly recorded that the patient had been taking methotrexate 7.5 mg weekly as an outpatient. But when he prescribed three 2.5 mg tablets weekly, it was transcribed incorrectly as three times daily. Upon transfer to another unit, the dose was transcribed incorrectly as three times a week. In each case the errors did not reach the patient because they were detected during pharmacy review of the order.

Similar errors have been reported overseas. For example, in Australia, one patient took extra doses of methotrexate as needed to relieve arthritic symptoms. Three elderly patients took the medication daily despite clearly written instructions to take it weekly. Two cases involved incorrect transcription of the dosing schedule with hospitalized patients. Three of the six patients died as a result of the errors.

Because of the number of fatalities from errors with oral methotrexate, clinicians should consider it a high alert medication. As such, there are several measures that can help reduce the risk of an error when oral methotrexate is prescribed:

- ◆ Build alerts in electronic prescribing systems and pharmacy computers to warn clinicians whenever doses of oral methotrexate have been entered (and to remind staff to check the indication with the patient in a community pharmacy setting). Configure the systems to avoid defaulting to a daily dosing schedule.
- ◆ Have a pharmacist conduct a prospective drug utilization review before dispensing oral methotrexate to determine its indication for use, verify proper dosing, confirm the correct dosing schedule on medication administration records and prescription labels, ensure staff and patient education, and promote appropriate monitoring of the patient.
- ◆ Establish a system that ensures outpatients receive counseling when picking up new prescriptions and refills (eg, mark the bag with a red flag to alert clerical staff that counseling is required, not optional).
- ◆ Provide patients with clear written instructions that name a specific day of the week for taking the tablet(s). When possible, avoid choosing Monday since it could be misread as "morning." Prepare instructions in large print to assist elderly patients with poor eyesight.
- ◆ Advise patients to contact their physician if they miss taking a dose. Tell them that a flare-up of the disease is unlikely with one missed dose.
- ◆ Ensure that written drug information leaflets are given to patients and that they contain clear advice about the weekly dosage schedule, not a daily dosing schedule.
- ◆ Explain to patients that taking extra doses is dangerous. Encourage feedback to ensure the patient understands the weekly dosing schedule and that the medication should not be used "as needed" for symptom control.
- ◆ Solicit help from a responsible caregiver if the patient appears to have cognitive or severe sensory difficulties.
- ◆ Prescribe the drug as a dose pack (eg, RHEUMATREX by Lederle), which helps to reinforce the weekly dosing schedule.

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3. When multiple stock bottles of a drug are used to fill a cell/cassette, all stock bottles used must be available for the pharmacist to check.
4. A system must be in place that addresses calibration, sanitation, and cross contamination.
5. Labeling of the vials, cells, or cassettes must be addressed as required in **MN Rule 6800.3200, Subp. 2**, to prevent errors.
6. Certification as required in **MN Rule 6800.3100, Subp. 3**, must be complied with and documented. Specifically how will a pharmacist check the original labeled container of a product from the automated counting machine? This must be determined and stated in your policies and procedures.
7. Those drugs that can be safely returned, can only be returned to the cell/cassette by a pharmacist. Co-mingling of lot numbers must be tracked and documented. Lot numbers not tracked and documented shall result in such medication being deemed misbranded and subject to embargo under **MN Statutes, §151.38**.
8. Implement a Quality Assurance/Quality Improvement monitoring system with concurrent corrective measures when necessary. See **MN Rule 6800.2400, Subp. 1.J.**, which states the pharmacist-in-charge, must ensure that staffing and operational quality assurance policies are developed, implemented, and followed for the purpose of decreasing and monitoring prescription errors.
9. Any proposed variance request that is a deviation from these rules must follow **MN Rule 6800.9900**, which states that any alternative measure taken must be equivalent or superior to current rules.

Rule Package Adopted

The Board has recently adopted the final language of the package of proposed rule changes that have been under development. As readers of this *Newsletter* will recall, the section of the proposed rules relating to lunch breaks for pharmacists was removed from the overall rule package and will be addressed at a public hearing later this year. The time and place of the public hearing have not yet been established.

The rest of the rule package originally proposed is in the process of being implemented and, by the time this *Newsletter* is published it is anticipated that the rules will be in effect.

The rule package contains requirements for minimum lighting standards in pharmacies, modification to the expiration date applicable to unit of use on blister card packaging done by pharmacists, rescheduling of certain controlled substances including Marinol®, application of the OBRA 90 patient counseling and DUR requirements to all patients, and modifications to the Board's internship requirements.

The full text of the Board's rules is available on the Board's Web site at www.phcybrd.state.mn.us.

June Board Exam Largest Ever

The Board exam administered June 4, 2002, was by far the largest ever conducted by the Board. Approximately 185 new graduates participated in the Board's practical examination. The previous record number was 157 candidates for licensure.

With the North American Pharmacist Licensure Examination™ (NAPLEX®) basic pharmacy practice exam and the Multistate Pharmacy Jurisprudence Examination™ (MPJE®) law exam now being offered on computer, the practical exam is the only portion of the Board exam where all of the candidates take the exam at the same time. In that exam (ie, NAPLEX and MPJE exams), candidates now make their own appointments for the NAPLEX and MPJE portions of the exams, scores are mailed out on a weekly basis rather than all at once.

Potential employers of new graduates are again cautioned not to schedule the individuals who took the June Board exam for work as pharmacists until the individual has received confirmation on passing the Board exam and has paid the original license fee. Only then can the individual begin his or her career as a pharmacist in Minnesota.

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